HYALTECH
A Carl Zeiss Meditec Company

DECLARATION OF CONFORMITY CERTIFICATE

MANUFACTURER:	Hyaltech Ltd. Starlaw Business Park Livingston, EH54 8SF, United Kingdom
PRODUCT:	**Fermathron** Synovial Viscosupplement device Product number: 030001 Biomet Reference number: 236380 - INT GMDN code: P44757
CLASSIFICATION:	Class III; Annex IX, Rule 8.
CONFORMITY ASSESSMENT ROUTE:	Annex II

We herewith declare that the above mentioned product meets the provisions of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained at the premises of the manufacturer.

STANDARDS APPLIED:	List of standards for which documented evidence for compliance can be provided
NOTIFIED BODY:	DEKRA Certification B.V. Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem The Netherlands Notified body number: 0344
EC CERTIFICATE:	2011354CE06
DESIGN EXAMINATION CERTIFICATE:	2011354DE04
START OF CE MARKING:	Originally CE marked on 08 September 1999 by MDC
FIRST CE BATCH:	3530AA manufactured December 2005
PLACE, DATE OF ISSUE:	Livingston, 11/2016
SIGNATURE:	25/11/2016 Michael Haisch Managing Director For and on behalf of Hyaltech Ltd.
SIGNATURE:	25 NOV 2016 Carolyn Melvin Regulatory Affairs Supervisor For and on behalf of Hyaltech Ltd.